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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,614	02/06/2006	Stefan Golz	Le A 36 493	6701
35969 7590 04/27/2010 Barbara A. Shimei Director, Patents & Licensing Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor Tarrytown, NY 10591				
EXAMINER				
LONG, SCOTT				
ART UNIT		PAPER NUMBER		
1633				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/537,614

**Applicant(s)**

GOLZ ET AL.

**Examiner**

SCOTT LONG

**Art Unit**

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 10-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10-13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

*The examiner acknowledges receipt of Applicant's Remarks and Claim amendments and Amendments to the Specification, filed on 20 April 2010.*

#### ***Claim Status***

Claims 1-4, 10-13 and 15-16 are pending. Claims 5-9, 14 and 17 are cancelled. Claims 15 is amended. Claims 1-4, 10-13 and 15-16 are under current examination.

#### ***Priority***

This application claims benefit as a 371 of PCT/EP03/13281 (filed 11/26/2003). The application also claims benefit from the foreign (German) patent application 10257354.9 (filed 12/9/2002). The instant application has been granted the benefit date, 9 December 2002, from the German application 10257354.9.

### **RESPONSE TO ARGUMENTS**

#### **35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Levine***

The rejection of claims 6 and 17 under 35 USC 102(b) as anticipated by Levine et al (Compar. Biochem. Physiol. B, 1982. 72; 1:77-86) is withdrawn due to the applicant's cancellation of claims 6 and 17.

***Tsien***

Claims 1-4, 10-13 and 15-16 remain rejected under 102(b) as being anticipated by Tsien et al. (US-5,777,079, published Jul. 7, 1998) for the reasons of record and the comments below.

The applicant's arguments and claim amendments have been fully considered but are unpersuasive.

The applicant has amended claim 15, combining elements of options c) and d). The previous anticipation rejection was based upon providing teachings which met the limitations of element c).

The applicant argues that as the Examiner's interpretation of option c) is unreasonable, based upon the plain meaning of option c). Furthermore, the applicant asserts that there is no evidence for concluding that one of ordinary skill in the art at the time of the instant invention would interpret the instant claim to mean "at least 95% homologous to only a small region or portion of SEQ ID NO:1." The examiner respects the applicant's view, regarding the examiner's claim interpretation. In fact, prior to

becoming a Patent Examiner, the examiner would have agreed with the applicant's view. However, since entering this field, the examiner has learned that the "plain meaning" of words is not always clear in law. Because of the ambiguity regarding the language used in claim directed to polynucleotide sequences and polypeptide sequences and to create some uniformity in examination practice, the Directors of TC1600 provided a Memo to guide examiners in how to interpret claims containing the phrase "SEQ ID NO." The examiner has provided a copy of this memo to applicant and cited it on the PTO-892 form. The relevant portion will be clear to the reader. The example which fits instant claim 15 is: "A nucleic acid comprising a nucleotide sequence of SEQ ID NO:1." The Office has decided that such a recitation "encompasses nucleic acids that comprise the full-length sequence of SEQ ID NO:1 or any portion of SEQ ID NO:1. This claim is anticipated by any dinucleotide or larger oligonucleotide." Therefore, the examiner feels he must interpret instant claim according to this directive. Accordingly, the examiner finds the applicant's argument unpersuasive.

In order to correct this language issue, the applicant might amend the word, "a" to "the" in the appropriate location within claim 15, or the applicant might introduce the word, "full-length" as appropriate. If the applicant wishes, he may contact the examiner to develop claim language which can overcome the pending rejection.

Therefore, the examiner hereby maintains the rejection of claims 1-4, 10-13 and 15-16 under 35 U.S.C. 102(b) as being anticipated by Tsien.

The examiner reiterates the pending rejection:

Claims 1-4, 10-13 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsien et al. (US-5,777,079, published Jul. 7, 1998).

Claim 1 is directed to an isolated nucleic acid molecules selected from the group consisting of:

- a) a nucleic acid molecule encoding a polypeptide having the amino acid sequence of SEQ ID NO:2;
- b) a nucleic acid molecule comprising the sequence of SEQ ID NO:1;
- c) a nucleic acid molecule which is at least 95% homologous to SEQ ID NO:1 whose complementary strand hybridizes under stringent conditions with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1, and encodes a fluorescent protein.

The examiner interprets option c) of claim 1 as requiring (1) only a small region of the claimed nucleic acid molecule as being 95% homologous to SEQ ID NO:1; (2) the complementary strand of the nearly any nucleic acid molecule (especially those taught by Tsien which encode fluorescent proteins) as being able to hybridize under stringent conditions with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1; and (3) the fluorescent proteins of Tsien (especially the mutant GFP which has an excitation peak of about 475 nm and an emission peak of about 493 nm) as encoding a fluorescent protein.

Tsien et al. teach modifications of green fluorescent protein having markedly different excitation and emission spectra from wild type GFP (abstract). Furthermore, Tsien et al. teach a mutant GFP which has an excitation peak of about 475 nm and an emission peak of about 493 nm (See Fig.3a and Fig.3b). Tsien et al. teach the nucleic acid sequence which encodes the mutant GFP. Furthermore, the complementary strand of the Tsien nucleic acid would hybridize under stringent conditions with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1. In addition, at least a portion of the Tsien mutant GFP is 95% homologous to SEQ ID NO:1, since the instant application teaches that the Tsien GFP is 44% homologous to the instantly claimed GFP. Additionally, the examiner interprets the phrase, "encodes a fluorescent protein" as referring to the nucleic acid molecule to which the claimed nucleic acid hybridizes (i.e., a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1). Optionally, the examiner can interpret the phrase "encodes a fluorescent protein" as referring to the nucleic acid molecule which encodes the GFP of Tsien.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Tsien et al. (US-5,777,079, published Jul. 7, 1998).

Claim 15 is directed to an isolated nucleic acid molecules selected from the group consisting of:

- a) a nucleic acid molecule encoding a polypeptide having the amino acid sequence of SEQ ID NO:2;

b) a nucleic acid molecule comprising the sequence of SEQ ID NO:1;

c) a nucleic acid molecule which is at least 95% homologous to SEQ ID NO:1 whose complementary strand hybridizes under stringent conditions with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1, and encodes a fluorescent protein having an excitation peak of about 475 nm and an emission peak of about 493 nm.

The examiner interprets option c) of claim 15 as requiring (1) only a small region of the claimed nucleic acid molecule as being 95% homologous to SEQ ID NO:1; (2) the complementary strand of the nearly any nucleic acid molecule (especially those taught by Tsien which encode fluorescent proteins) as being able to hybridize under stringent conditions with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1; and (3) the fluorescent proteins of Tsien (especially the mutant GFP which has an excitation peak of about 475 nm and an emission peak of about 493 nm) as encoding a fluorescent protein having an excitation peak of about 475 nm and an emission peak of about 493 nm.

Tsien et al. teach modifications of green fluorescent protein having markedly different excitation and emission spectra from wild type GFP (abstract). Furthermore, Tsien et al. teach a mutant GFP which has an excitation peak of about 475 nm and an emission peak of about 493 nm (See Fig.3a and Fig.3b). Tsien et al. teach the nucleic acid sequence which encodes the mutant GFP. Furthermore, the complementary



strand of the Tsien nucleic acid would hybridize under stringent conditions with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1. In addition, at least a portion of the Tsien mutant GFP is 95% homologous to SEQ ID NO:1, since the instant application teaches that the Tsien GFP is 44% homologous to the instantly claimed GFP. Additionally, the examiner interprets the phrase, "encodes a fluorescent protein" as referring to the nucleic acid molecule to which the claimed nucleic acid hybridizes (i.e., a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1).

Tsien also teaches vectors (claims 3 and 11) comprising nucleic acids encoding mutant GFP; host cells (claim 4); promoters (claim 2); inducible promoters (claim 12); methods of using fusion proteins (claim 10); methods of producing a fluorescent protein (claims 13 and 16).

Therefore, Tsien et al. anticipated the instant claim.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Scott Long/  
Patent Examiner  
Art Unit 1633